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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,684	11/14/2003	Tilla S. Worgall	66854-A/JPW/AJM/JCS	9072

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John P. White
Cooper & Dunham LLp
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,684	WORGALL ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-16 and 44-49* is/are pending in the application.

4a) Of the above claim(s) *11,13-16 and 44-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and active myriocin (enzyme ceramide synthase) in the reply filed on 31 January 2007 is acknowledged. The traversal is on the ground(s) that no serious burden is put on the Examiner to search and examine the entire claimset. This is not found persuasive because not only is there a serious burden on the Examiner but the standard for finding the claims independent and distinct has also been met. As noted in the Restriction Requirement, claims 13-16 for example are directed to a method which is the polar opposite of claims 1 and 5-12 (a method of increasing mSREBP vs. a method of decreasing mSREBP) and are therefore not capable of use together, have a materially different design, mode of operation, function, effect and are mutually exclusive. Claims 11, 13-16 and 44-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Moreover, new claims 44-49 are directed to an invention that is independent or distinct from the invention originally claimed and elected for the following reasons: a method for determining whether an agent decreases de novo synthesis of ceramide (claim 49) is different in design, mode of operation, function and effect than a method of decreasing mSREBP in a cell. Further, the method of claims 44-48 comprise treating a disease wherein the diseases are independent and distinct from each other, for example a method which comprises the treatment of hypertriglyceridemia as compared to one which treats syndrome X or

alcoholism. The distinctness of claims 44-48 from Group I rests in the effects of the claim directive. Group I is directed to decreasing the amount of mSREBP whereas claim 44, for example, is directed to treating diseases and to that extent will differ from Group I in terms of patient population, patient sensitivities and the precise objectives of the claim. To that end, the search for Group I is not coextensive with the search for Group II which will in turn be a search burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Status of Action

Claims 1, 5-10 and 12 are examined.

Specification

The abstract of the disclosure is objected to because the abstract contains the word "comprising". Applicant is reminded that the abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "comprising," as in line 2 of the instant abstract should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 8-9, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Riley et al. Serine palmitoyltransferase inhibition reverses anti-proliferative effects of ceramide synthase inhibition in cultured renal cells and suppresses free sphingoid base accumulation in kidney of BALBc mice. Environmental Toxicology and Pharmacology 7 (1999) 109-118.

Riley et al. teach BALBc mice treated with myriocin (see page 113) wherein it is known that myriocin (an SPT inhibitor) is known to reduce the fumonisin-induced accumulation of free sphingoid bases in vivo and that fumonisins can block ceramide generated de novo (see page 116 second column). Riley et al. also teaches a method wherein the myriocin is dosed to BALBc mice (see page 113) which in turn teaches that the myriocin comes into contact with cells such as liver cells (see page 114). The same concept is concluded on page 117 wherein Riley et al. teach that the ability of SPT inhibitors (myriocin) is able to inhibit de novo ceramide biosynthesis in the liver, kidney and heart for example in animals. That the reference does not specifically state a decrease in mSREBP is of no moment since a compound and its properties are inseparable. To that extent, the reference teaches the contacting of myriocin to

hepatocytes and wherein the myriocin will function according to its nature thereby reading on the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley et al. Serine palmitoyltransferase inhibition reverses anti-proliferative effects of ceramide synthase inhibition in cultured renal cells and suppresses free sphingoid base accumulation in kidney of BALBc mice. Environmental Toxicology and Pharmacology 7 (1999) 109-118.

Riley et al. teach BALBc mice treated with myriocin (see page 113) wherein it is known that myriocin (an SPT inhibitor) is known to reduce the fumonisin-induced accumulation of free sphingoid bases in vivo and that fumonisins can block ceramide generated de novo (see page 116 second column). The same concept is concluded on page 117 wherein Riley et al. teach that the ability of SPT inhibitors (myriocin) is able to inhibit de novo ceramide biosynthesis in the liver kidney and heart for example in animals. That the reference does not specifically state a decrease in mSREBP is of no moment since a compound and its properties are inseparable. To that extent, the reference teaches the contacting of myriocin to hepatocytes and wherein the myriocin will function according to its nature thereby reading on the claims. Although Riley et al. do not specifically teach myriocin contacting adipocytes, the myriocin is taught to be feed to BALBc mice (see page 113) the result of which was detected in the liver, blood and kidney. Examiner interprets the claim language "comprising contacting the cell with an agent..." to mean that the active contacts the outermost part of a cell at the minimum which would then include the active being transported to an adipocyte in the blood. With the teaching of feeding myriocin to animals along with the teaching that ceramide is inhibited in many cell types (see page 117), one of ordinary skill in the art would understand that adipocytes, which are located throughout the body, will be contacted by myriocin when feed to animals. Additionally, Riley et al. does not specifically recite human trials but compares clinical trials to the warranting of animal trials therefore alluding to human clinical trials. Thus, the reference makes prima facie obvious how to use the claimed invention at the time that it was made.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 May 2007
MG

Ardin H Marschel 5/27/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER